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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------|
| 10/608,200 | 06/27/2003 | Jean-Marc Payrat | F-4066 DIV CONT DIV II | 8009 |
| 7590 | 11/23/2005 | | EXAMINER | |
| Michael C. Mayo Baxter Healthcare Corporation Fenwal Division, RLP-30, Route 120 & Wilson Road P.O. Box 490 Round Lake, IL 60073 | | | SAUCIER, SANDRA E | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1651 | |
| | | | DATE MAILED: 11/23/2005 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/608,200 | PAYRAT ET AL. | |
| | Examiner | Art Unit | |
| | Sandra Saucier | 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 37-41 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 37-41 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 6/27/03 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|--|
| <ol style="list-style-type: none"> 1)<input type="checkbox"/> Notice of References Cited (PTO-892) 2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3)<input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>10/8/03</u>. | <ol style="list-style-type: none"> 4)<input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____. 5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6)<input type="checkbox"/> Other: _____. |
|---|--|

DETAILED ACTION

Claims 37–41 are pending and are considered on the merits.

Specification

The disclosure is objected to because of the following informalities: The first paragraph of the specification should have the status of 09/268,405 updated. Appropriate correction is required.

Information Disclosure Statement

The listing of the references on PTO 1449 is incomplete. A proper citation includes AUTHOR, TITLE, JOURNAL, VOLUME, NUMBER, INCLUSIVE PAGES, (month), YEAR. **The citations crossed out are incomplete and are missing either journal name, page number or year of publication.** A citation to a portion of a book requires title of the book, publisher, place of publication, editor(s), year of publication. Reference AT is missing every other page as well as having an incomplete citation.

MPEP37 CFR 1.98(b) requires that each U.S. patent listed in an information disclosure statement be identified by patentee, patent number, and issue date. Each foreign patent or published foreign patent application must be identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application. Each publication must be identified by author (if any), title, relevant pages of the publication, date and place of publication. The date of publication supplied must include at least the month and year of publication, except that the year of publication (without the month) will be accepted if the applicant points out in the information disclosure statement that the year of publication is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the particular month of publication is not in issue. The place of publication refers to the name of the journal, magazine, or other publication in which the information being submitted was published.

Claim Rejections - 35 USC § 112

NEW MATTER

Claims 37-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Insertion of the limitation "substantially free of chloride" has no support in the as-filed specification. The insertion of this limitation is a new concept because it expands the scope of the disclosure. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter.

While it may be argued that there is support for the phrase "which solution does not include sodium chloride" on page 4, Summary of Invention, line 10, this is not the same as "substantially free of chloride", which is a broadening of the original disclosure.

Please see Gentry Gallery v. Berkline 45 U.S.P.Q.2d 1498 for a discussion related to broadening the claimed invention without support in the as-filed specification.

INDEFINITE

Claims 37-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 uses the term "concentrated" which is a term of comparison without a point of reference. Insertion of a hematocrit value would overcome this rejection.

Claim 40 is indefinite because it is unclear if applicants intend the composition to be limited to 75-100mls of the solution or if applicant are attempting to claim a product by process.

Claim 41 is indefinite because it is unclear if it is directed to a product or a process. It is neither a product-by-process claim, nor is it a process claim. It has been treated as a composition claim for the purposes of examination. See MPEP 2173.05(p).

Claim 37 is objected to because it is missing "/l" after mmol in line 7.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37-41 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 5,250,303 [CG].

The claims are directed to a composition comprising red cells suspended in a solution containing:
about 30-60 mM dextrose (45.4mM),
about 1.2-1.7 mM adenine (1.5mM),
about 30-50 mM mannitol (40mM),
about 4.5-55 mM sodium citrate (25mM),
about 2-5 mM sodium diphosphate (3.9mM),
about 8-18 mM sodium phosphate dibasic (16.1mM),

substantially free of chloride and with an osmolarity of less than 300 mOsm.

US 5,250,303 discloses a composition comprising:
red cells suspended in a solution containing:

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dextrose (50mM),
adenine (0.01M)
sodium citrate (22mM),
mannitol (44mM),
sodium dihydrogen phosphate (2.5mM),
sodium phosphate dibasic (10.6mM), pH 7.5, osmolality around 200.

as exemplified in Table 2, ARC 30.

Use of the term "about 1.2-1.7mM adenine" may be argued to permit inclusion of 0.01mM adenine.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 37-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,250,303[CG].

The claims are directed to a composition comprising red cells suspended in a solution containing:

about 30-60 mM dextrose (45.4mM),
about 1.2-1.7 mM adenine (1.5mM),
about 30-50 mM mannitol (40mM),
about 4.5-55 mM sodium citrate (25mM),
about 2-5 mM sodium diphosphate (3.9mM),

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about 8-18 mM sodium phosphate dibasic (16.1mM),

substantially free of chloride and with an osmolarity of less than 300 mOsm.

Dependent claim concentrations are in parenthesis and include a pH of about 7.4.

US 5,250,303 discloses compositions comprising:

red cells suspended in a solution containing:

50-139mM dextrose (50mM),

0.01-2mM adenine (0.01M)

22-33mM sodium citrate (22mM),

mannitol (44mM),

2.5-2.9 mM sodium dihydrogen phosphate (2.5mM),

10.6-12mM sodium phosphate dibasic (10.6mM),

pH 7.4-7.5, osmolality around 200mOs.

as exemplified in Table 2, ARC8, ARC 27, ARC30.

Although the specifically exemplified ARC30 has only 0.01mM adenine, use of the terms "approximately" which lack definition in the specification permits application of the reference. Further, adenine is shown to be present in similar solutions in concentrations up to 2mM. Generally, differences in concentration will no support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. This is considered to be routine experimentation well within the purview of one of skill in the art in the absence of evidence to the contrary. See MPEP 2144.05 I. and II.

One of ordinary skill in the art would have been motivated at the time of invention to make these changes in concentrations in order to obtain the resulting composition as suggested by the reference with a reasonable

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expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to the office action.

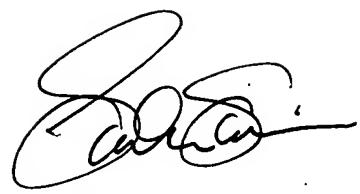
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Sandra Saucier
Primary Examiner
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November 21, 2005